K023648

510(k) CONTENT SUMMARY

1. Name of Manufacturer:

Sun Biomedical Laboratories Inc.
604 VPR Center
1001 Lower Landing Road
Blackwood, NJ 08012

MAY 0 6 2003

2. Trade Name: Visualine® Cup VI for Drugs of Abuse Test for Qualitative determination of Cocaine, Cannabinoids, Morphine, Methamphetamine or Amphetamines, Phencyclidine and Benzodiazepines and/or their metabolites in Human Urine Samples.

3. Common Name:

An in-vitro immunoassay, multi-drug test panel using visual color comparison for the detection of Cocaine, Cannabinoids, Morphine, Methamphetamine or Amphetamines, Phencyclidine, and Benzodiazepines in human urine samples.

4. Regulation # and Classification:

Reg. #862-3170, Class II Device

5. Test Description:

The Visualine® CupVI for Drugs of Abuse Test is based on the principle of antigen-antibody complexation and is used for the analysis of Cocaine, Cannabinoids, Morphine, Methamphetamine or Amphetamines, Phencyclidine, and Benzodiazepines and their corresponding metabolites in human urine samples. The assay utilizes a competitive immunochromatographic technique involving a sample of test urine delivered through a wicking action as the test panel (holding the porous membrane) is dipped into the urine sample. The drug in the sample competes for the limited antibody sites on the colored microspheres. When an adequate amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored microspheres to the probe site on the membrane. Therefore, a positive urine sample will inhibit the formation of precipitin at the probe site.

A reference or control line with a secondary antibody reaction is added to the membrane strip to check for proper sample migration on the membrane. This control line should always be present. A negative urine sample will produce two colored lines and a positive urine sample will show only one, the control line.

6. Comparison of Two Test Systems for Correlation Studies:

The Visualine® Cup VI for Drugs of Abuse Test for Qualitative Determination of Cocaine, Cannabinoids, Morphine, Methamphetamine or Amphetamines, Phencyclidine, and Benzodiazepines assay is correlated to the Sub Biomedical's existing Visualine® V Drugs of Abuse Test and the Visualine® II Benzodiazepine assay and Visualine® II Amphetamine drugs of abuse assay. The following table illustrates the similarities and differences between the assays.

	Visualine®V Drugs of Abuse Test for Qualitative Determination of Cocaine, Cannabinoids, Morphine, Methamphetamine, and the Visualine® II Drugs of Abuse Assay for Benzodiazepines and Amphetamines	Visualine®Cup VI for Drugs of Abuse Test for Qualitative Determination of Cocaine, Cannabinoids, Morphine, Methamphetamine or Amphetamines, Phencyclidine and Benzodiazepines
Test Principle	Competitive binding	Competitive binding
Sample/Sample Size	Approx. 200 ul urine/test strip	Approx. 200 ul urine/test strip
Antibody	Polyclonal and Monoclonal	Polyclonal and Monoclonal
Tracer	Ab Colloidal Gold	Ab Colloidal Gold
Detection Method	Visual color precipitin formation	Visual color precipitin formation
Test Run Time	5 minutes	5 minutes
Storage Requirements	2-10°C (36-86°F)	2-10°C (36-86°F)
Detection Levels:		
Cocaine	300 ng/ml	300 ng/ml
Cannabinoids	50 ng/ml	50 ng/ml
Morphine	300 ng/ml	300 ng/ml
Methamphetamine	1000 ng/ml	1000 ng/ml
Phencyclidine	25 ng/ml	25 ng/ml
Benzodiazepines	300 ng/ml	300 ng/ml
Amphetamines	1000 ng/ml	1000 ng/ml
Ancillary Equipment	none	none

7. Visualine® Cup IV Test Performance Characteristics:

A. Correlation studies between Visualine® V Drugs of Abuse Test and Visualine® II drugs of Abuse Test for Cocaine and it's metabolites, Cannabinoids and it's metabolites, Morphine and it's metabolites, Methamphetamine or Amphetamines and their metabolites, Phencyclidine, and Benzodiazepines and it's metabolites were conducted at Redwood Toxicology Laboratory, Santa Rosa California and at Sun Biomedical Laboratories. The presumptive positive samples were provided by Redwood and assayed on the Hitachi at Redwood followed by testing by the Visualine® V Test, Visualine® Cup VI, and Visualine® II Benzodiazepine and Amphetamine tests. Negative samples consisted of UTAK Laboratories Drug Free Urine pool #5488, and in-house negative urines tested with Sun Biomedical's Visualine®II product for the targeted drugs of abuse. The following information represents the correlation between the new Visualine® Cup VI Test and the existing Visualine® V Test, the Visualine® II Benzodiazepine and Amphetamine Tests.

Cocaine:	Positive Agreement	42/43	97.7%
	Negative Agreement	381/381	>99%
	Overall Agreement	423/424	>99%
Cannabinoids	Positive Agreement	46/48	96%
	Negative Agreement	376/376	>99%
	Overall Agreement	424/424	>99%
Morphine:	Positive Agreement	48/48	>99%
	Negative Agreement	375/376	>99%
	Overall Agreement	424/424	>99%
Methamphetamine:	Positive Agreement	47/47	>99%
	Negative Agreement	377/377	>99%
	Overall Agreement	424/424	>99%
Phencyclidine:	Positive Agreement	46/46	>99%
	Negative Agreement	378/378	>99%
	Overall Agreement	424/424	>99%
Benzodiazepines:	Positive Agreement	55/55	>99%
	Negative Agreement	369/369	>99%
	Overall Agreement	424/424	>99%
Amphetamines	Positive Agreement	40/42	95%
	Negative Agreement	382/382	>99%
	Overall Agreement	424/424	>99%

B. Specificity and Substances Detected:

The individual tests are specific to the labeled drug of abuse or structurally related compounds. The test detects Cocaine and it's metabolites at 300 ng/ml, Cannabinoids and it's metabolites at 50 ng/ml, Morphine and it's metabolites at 300 ng/ml, Methamphetamine or Amphetamines at 1000 ng/ml, Phencyclidine at 25 ng/ml, and Benzodiazepine (Oxazepam) and it's metabolites at 300 ng/ml.

C. Precision:

Reproducibility studies for Visualine® Cup VI for Cocaine, Cannabinoids, Morphine, Methamphetamine, Amphetamine, PCP, and Benzodiazepines indicate:

Within run and run to run	>99%
Within day and day to day	>99%
Within lot and lot to lot	>99%

D. Stability Statement:

Visualine® Cup VI Test stability has been studied. The urine drugs tests are tested every three months and reviewed for acceptance by the Quality Control Manager, also every three months, for up to a period of over two years. The acceptance criteria are as follows: A urine specimen containing 0 ng/ml of the analyte of interest will render two distinct magenta lines, one test line and one control line. Samples containing +25% of cutoff analyte levels will show positive results >99% of the time, therefore yielding only the control line. Visualine® Cup VI Tests are stable within their marked expiration date and under the storage conditions as described in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 0 6 2003

Ming Sun, Ph.D.
Sun Biomedical Laboratories Inc.
604 VPR Center
1001 Lower Landing Road
Blackwood, NJ 08012

Re: k023648
Trade/Device Name: Visualine® Cup VI for Drugs of Abuse Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ; DIO; DJG; DJC; LCM; JXM;
Dated: January 30, 2003
Received: March 5, 2003

Dear Dr. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SUN BIOMEDICAL LABORATORIES, INC.

604 VPR CENTER, 1001 LOWER LANDING ROAD, BLACKWOOD, NJ 08012
Tel. 856-401-1080 Fax. 856-401-1090

510 (k) Number: K023648

DEVICE NAME: Visualine®Cup VI for Drugs of Abuse Test

INDICATIONS FOR USE: The Visualine®Cup VI for Drugs of Abuse Test is used for qualitative testing for the presence of Cocaine and it's metabolites at or above 300 ng/ml, Cannabinoids and it's metabolites at or above 50 ng/ml, Morphine and it's metabolites at or above 300 ng/ml, Methamphetamine at or above 1,000 ng/ml, Amphetamine at or above 1,000 ng/ml, Phencyclidine at or above 25 ng/ml, and Benzodiazepines and it's metabolites at or above 300 ng/ml in human urine samples. This test provides only a preliminary screening result; a more specific alternative method should be used to confirm the test result. This test is intended for use by medical professionals.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023648

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter-Use _____

(Per 21 CFR 801.109) OR (Optional Format 1-2-96)